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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,046	10/15/2003	Joseph W. St. Geme III	A-59941-4 (467084-68)	7511

7590 07/09/2004

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EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/687,046	ST. GEME, JOSEPH W.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jennifer E. Graser	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. Claims 3-7 are currently pending and correspond to Group II of the Restriction Requirement. Applicants properly responded to the Restriction Requirement mailed 5/13/04 by stating that claims 1-2 and 8-16 were previously canceled in the Preliminary Amendment of October 15, 2003. This Preliminary Amendment was not properly entered at the time the Examiner issued the Restriction Requirement. Correction has been made. Apologies are made for any inconvenience to Applicants.

Claims 3-7 are currently pending and under examination.

### ***Specification/Priority***

2. This application filed under former 37 CFR 1.60 lacks the necessary updated reference to the prior applications. The first line of the specification must be amended to include proper reference to all of the prior applications. Also, the current status of all nonprovisional parent applications referenced should be included. For instance:

This application is a DIV of 10/080,505 02/22/2002 PAT 6,676,948

which is a CIP of 08/296,791 08/25/1994 PAT 6,245,337

and is a CIP of 09/839,996 04/20/2001 PAT 6,642,371

which is a DIV of 08/296,791 08/25/1994 PAT 6,245,337.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite the phrase "high stringency conditions" is vague and indefinite because hybridization conditions can vary considerably. A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration and salt concentration. Changes in these parameters will affect the specificity of the binding. Thus, in order to ascertain the metes and bounds of the patent protection, the skilled artisan would require a knowledge of these specific parameters. The claim does not clearly and unambiguously set forth the appropriate reaction conditions. The rejection may be overcome by clearly setting forth the reaction conditions encompassed by a stringent hybridization, as supported by the disclosure. For example, "high stringency conditions of washes at 0.1 X SSC at 65 Degrees Celsius for 2 hours". Support must be provided in the specification for whatever limitations are added.

Claims 3 and 4 are vague and confusing because independent claim 3 describes a recombinant nucleic acid that is able to hybridize under high stringency conditions to a nucleic acid selected from the group consisting of the sequence shown in SEQ ID Nos: 8, 10, 12, 14 and 16, and claim 4 (which depends from claim 3) recites that the nucleic acid is identical to that shown in the sequence selected from the group consisting of the sequence shown in SEQ ID Nos: 8, 10, 12, 14 and 16. Thus, the claims read on a

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recombinant nucleic acid that will hybridize to itself. It is unclear if Applicants intend to claim both a sequence which will hybridize to SEQ ID Nos: 8, 10, 12, 14 and 16 (then, it could not also be SEQ ID Nos: 8, 10, 12, 14 and 16) and also the nucleic acid set forth in the claims. Clarification and amendment to the claims is required.

Claim 7 is vague and indefinite because it recites a method for producing *any Haemophilus* and adhesion protein. The claims are drawn to recombinant methods of making the protein, but neither the nucleic acid encoding sequence or the amino acid sequence of the protein is disclosed. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Falkow et al (WO 96/05858) . **(NOTE:** The instant claims are only entitled to priority back to US Application 10/080,505, a priority date of 2/22/02. The sequences set forth in SEQ ID Nos: 8, 10, 12, 14 and 16 did not appear until this application so they are not entitled to the earliest filing date.)

Falkow et al teach an isolated nucleic acid encoding a *Haemophilus* adhesion and penetration protein which has a local similarity of 82.3% and an overall similarity of 61.5% to SEQ ID NO: 16; a local similarity of 79.6% and an overall similarity of 57.4% to SEQ ID NO: 14; a local similarity of 82% and an overall similarity of 57% to SEQ ID NO: 12; a local similarity of 79.4% and an overall similarity of 58.8% to SEQ ID NO: 10; a local similarity of 85.7% and an overall similarity of 73.9% to SEQ ID NO: 8. This double stranded nucleic acid would hybridize under the conditions specified in claim 3. Expression vectors and host cells containing the DNA are taught as well as recombinant methods of producing the protein.

7. Claims 3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al (WO 96/33276) . **(NOTE:** The instant claims are only entitled to priority back to US Application 10/080,505, a priority date of 2/22/02. The sequences set forth in SEQ ID Nos: 8, 10, 12, 14 and 16 did not appear until this application so they are not entitled to the earliest filing date.)

Adams et al teach an isolated nucleic acid which has a local similarity of 78.6% and an overall similarity of 62.9% to SEQ ID NO: 16; a local similarity of 82.9% and an

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overall similarity of 70% to SEQ ID NO: 14; a local similarity of 86.8% and an overall similarity of 76.6% to SEQ ID NO: 12; a local similarity of 83% and an overall similarity of 70.6% to SEQ ID NO: 10; a local similarity of 82.7% and an overall similarity of 70% to SEQ ID NO: 8. This double stranded nucleic acid would hybridize under the conditions specified in claim 3. Expression vectors and host cells containing the DNA are taught as well as recombinant methods of producing the protein.

8. Claims 3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by St.Geme et al (Molec. Biol. 1994. 14(2): 217-233) . **(NOTE:** The instant claims are only entitled to priority back to US Application 10/080,505, a priority date of 2/22/02. The sequences set forth in SEQ ID Nos: 8, 10, 12, 14 and 16 did not appear until this application so they are not entitled to the earliest filing date.)

St. Geme et al each an isolated nucleic acid which has a local similarity of 82.4% and an overall similarity of 62% to SEQ ID NO: 16; a local similarity of 79.7% and an overall similarity of 58.0% to SEQ ID NO: 14; a local similarity of 82.1% and an overall similarity of 57.5% to SEQ ID NO: 12; a local similarity of 79.4% and an overall similarity of 59.4% to SEQ ID NO: 10; and a local similarity of 85.7% and an overall similarity of 74.2% to SEQ ID NO: 8. This double stranded nucleic acid would hybridize under the conditions specified in claim 3.

9. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Fleischmann et al (Science. 1995. 269(5223): 496-512) . **(NOTE:** The instant claims are only entitled to priority back to US Application 10/080,505, a priority date of 2/22/02. The sequences

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set forth in SEQ ID Nos: 8, 10, 12, 14 and 16 did not appear until this application so they are not entitled to the earliest filing date.)

Fleischmann et al teach an isolated nucleic acid which has a local similarity of 78.2% and an and an overall similarity of 60.5% to SEQ ID NO: 16; a local similarity of 82.8% and an and an overall similarity of 62.9% to SEQ ID NO: 14; a local similarity of 86.4% and an overall similarity of 72.3% to SEQ ID NO: 12; a local similarity of 82.3% and an overall similarity of 65.7% to SEQ ID NO: 10; a local similarity of 82.8% and an overall similarity of 70% to SEQ ID NO: 8. This double stranded nucleic acid would hybridize under the conditions specified in claim 3.

***Allowable Subject Matter***

11. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

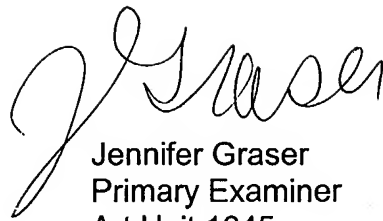
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.



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 7/7/04  
Jennifer Graser  
Primary Examiner  
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